



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration,
College Park, MD 20740

AUG - 4 2004

Mr. Robert A. Mangini, Jr.
President
Physician Health Station LLC
dba Physician Health Network
4730 East Indian School Road
Suite 120-208
Phoenix, Arizona 85018

Dear Mr. Mangini:

This is in response to your letter of May 25, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Physician Health Network is making the following claims, among others, for the following products:

Female Care

"[P]romote wound healing."

L-Carnitine

"[P]romoting...wound healing after a burn or injury.

"[B]reak down cholesterol, promoting cardiovascular health."

MSM Capsules

"[P]roviding relief for injury inflammation and soreness...."

"[A]lleviate the unfortunate consequences of injury...."

Inflammation Formula

"[R]educe inflammation, to promote healing and relieve pain instead of simply masking pain."

"[R]elieve minor pain associated with...injury."

Kava Kava Extract

"[R]elieving pain and inflammation resulting from...an injury."

Glucosamine/Chondroitin

"[R]educe pain...occasional overuse."

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Page 2 - Mr. Robert A. Mangini, Jr.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases such as injuries and wounds, joint disease, and high cholesterol and heart disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

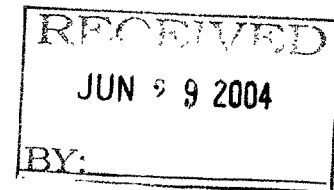
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

Physician Health Network

May 25, 2004

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, D.C. 20204



Dear Sir or Madam:

The purpose of this letter is to provide notification pursuant to Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act (the "Act") and 21 C.F.R. § 101.93 that Physician Health Station LLC (d/b/a Physician Health Network) ("PHN") has begun marketing and distributing certain dietary supplements that bear the following structure/function statements as defined in § 403(r) (6) of the Act:

Multi-Life (multi-vitamin):

- Numerous benefits include: cell renewal; cardiac support; vision protection; glowing, healthy skin; stress and environment-battling antioxidants; enhanced brain processes and neurological function to include improved memory, learning, and concentration.
- A multi-vitamin with staying power, Multi Life's vitamins, minerals, antioxidants, and enzymes break down at a progressive rate throughout the day, providing a consistent surge of energy for all of life's challenges.

Female Care:

- Vitamins A, C, and E provide for: vibrant, youthful skin; healthy, shiny hair; protection of vision clarity; antioxidant protection from free radicals and pollutants.
- The additions of Magnesium, Iodine, Zinc, and Calcium: create stronger bones and teeth; maintain normal muscle and nerve function; shield the cardiovascular and respiratory systems; strengthen the immune system and promote wound healing.
- A unique inclusion of Soy Isoflavones provides estrogen and hormonal balance support.
- The vitamins and minerals both generate the needed energy for an activity-filled day, yet also create a calming effect for a night of restful sleep.

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B-50 Complete:

- As a complex formula, B-50 will: stimulate skin cell renewal; produce red blood cells for a healthy nerve system and healthy heart; act as an antioxidant, defending the body against outside, harmful pollutants; maintain and build healthy eyes, hair, liver, and gastrointestinal tract.
- B Vitamins are known to relieve stress and soothe the body after exposure to environmental toxins such as the sun, or lifestyle habits to include smoking, poor diet, or alcohol consumption.
- Taken regularly, B-50 Complete will give you the energy to lead the life you have always wanted.

Calcium Lactate:

- A necessary mineral, Calcium Lactate: builds and maintains strong, healthy bones and teeth; restructures bone mass for those with bone loss; increases strength of weak bones and muscles; regulates the heart beat, aiding muscle contraction and relaxation.
- Taken regularly, Calcium Lactate will construct your bones, muscle, and tissue, elements necessary for an active, healthy lifestyle.

DHEA:

- In regards to health and longevity, DHEA: stimulates bone development and the maintenance of bone mass; generates the sex hormones, estrogen and testosterone; improves neurological function; strengthens immune system; increases muscle.
- Vitamin C is included in the supplement, as it is important to protect the liver with an antioxidant while taking a natural hormone. Taken accordingly at 1 to 2 capsules daily, or as otherwise directed, DHEA will result in deeper sleep, a better ability to cope with daily stress, and a greater sense of calm and well being.

Black Cohosh Extract:

- Although commonly recommended to ease the symptoms of menopause for women, Black Cohosh also has beneficial qualities for children and men.
- A remedy used for many years, Black Cohosh: relieves the tension of muscle aches to include lower back pain and menstrual cramping; provides minor pain relief; supports healthy lung and brachial passageway function; helps relieve anxiety.
- Ease the symptoms of PMS and menopause.

Alpha-Lipoic Acid:

- ALA: fends off and neutralizes free radicals, molecules with unstable cellular components that ultimately damage our cellular system; repairs damage by increasing production of Glutathione, a major repair enzyme that dissolves toxic substances; has protective and oxidative processes that defend against premature aging.
- Alpha-Lipoic Acid helps: maintain healthy blood sugar and cholesterol levels that are already within the normal range; support cardiovascular health; support healthy eye function.
- Antioxidant for a healthy heart and anti-aging.

Co-Enzyme Q10:

- A strong antioxidant, Co-Enzyme Q10 fends off and neutralizes free radicals, molecules with unstable cellular components that ultimately damage our cellular system.
- Optimal amounts taken may provide the following benefits: support heart health and healthy blood pressure that is already within the normal range; support gum health; nutritionally supports and stimulates the immune system.
- Taking 1 or more capsules daily with meals or as otherwise directed, Co-Enzyme Q10 will act as a contaminant-fighting shield and result in an energized, supremely functioning body.

Complex Omega 3 & 6:

- When taken in balanced amounts, Omega 3 and 6 are polyunsaturated fatty acids or "good" fats, which: supports joint health; ensure optimal cardiac function and maintain blood pressure that is already within the normal range; relieve discomforts of PMS and improves menstrual comfort; promotes healthy skin and reduces occasional acne; nourish brain function, support mood and a normal healthy attitude; compliment a pregnant mother's natural levels for proper development of the brain and organs of the fetus.
- Taking 1 capsule daily with meals or as otherwise directed, Complex Omega 3 & 6 may help you slim down, and provide a greater sense of well-being.

Green Tea Extract:

- Its properties aid several organs to include the skin, liver, and heart.
- Green Tea Extract will: maintain cholesterol levels that are already within the normal range; relieve minor pain, including muscle pain following exercise; support respiratory and digestive health; assist digestion in those experience metabolic difficulties; shown to treat occasional acne to produce a lighter, more glowing complexion; ensure the proper functionality and defense of the liver in digestion of food and metabolism of alcohol.
- Taking 1 capsule twice daily or as otherwise directed, Green Tea Extract will improve your overall mood and feeling of well-being.

L-Carnitine:

- A therapy for low energy levels and used to support heart health and enhance the immune system, L-Carnitine functions as a catalyst, assisting the conversion of fats and sugars into energy. Doing so, it nourishes the heart, muscle and circulatory system. It also helps break down cholesterol, promoting cardiovascular health.
- L-Carnitine is beneficial for nearly everyone by: developing firm, lean muscle tissue; burning fat to increase energy levels; promoting scar and wound healing after a burn or injury; supporting muscle, liver and kidney health; aiding in dieting as it reduces hunger triggers, therefore curbing your appetite.

Milk Thistle Seed Extract:

- Milk Thistle: regenerates injured liver cells; enriches skin cells and promotes healthy skin; alters the makeup of bile, promoting digestinal health; reduces inflammation in the vascular system to smooth circulation and protect against the development of spider veins; promotes vascular system health.
- Milk Thistle has been clinically shown to promote healthy liver function.

Saw Palmetto Extract:

- It is the leading men's supplement due to its renowned maintenance of prostate function and urinary health.
- Regular use of Saw Palmetto supports both daytime and nighttime healthy function of the urinary passages.
- Taking 1 capsule twice daily or as otherwise directed, Saw Palmetto Extract can support proper prostate function, putting one's mind at ease.

MSM Capsules:

- MSM, or Methyl-sulfonyl-methane, has proven to provide relief for minor pain.
- Taken as a supplement, MSM benefits by: providing relief for injury inflammation and soreness, and muscle pain following exercise; increasing blood flow to areas of pain and inflammation, promoting the healing process; supporting joint health; assisting the formation of keratin, the nutrient responsible for brilliant, strong hair and nails; maintaining high levels of immune system protective elements in the body.
- 1 capsule taken 1 to 3 times daily or as otherwise directed should alleviate the unfortunate consequences of injury or the aches and pains that accompany the natural aging process.

Glucosamine/Chondroitin:

- Stimulate the production of new cartilage, or joint “cushion.”
- Absorb water from the body to keep joints flexible.
- Glucosamine and Chondroitin are shown to help build and support joint cartilage, assist in maintaining overall joint health, and promote enhanced mobility.
- This supplement can also help reduce pain and stiffness due to occasional overuse.

Inflammation Formula (containing New Zealand Green Lipped Mussel extract):

- Inflammation Formula Capsules provide an effective, safe, natural alternative for the relief of minor pain.
- Inflammation Formula Capsules (with ETARol): ingredients have been proven to reduce inflammation, to promote healing and relieve pain instead of simply masking pain; may help relieve minor pain associated with exercise and injury; no reported gastrointestinal irritation.

5-HTP:

- 5-HTP can provide the following benefits: relieve anxiety; enhance sleep; suppress the appetite; enhance cognitive development; provide relief for minor pain; support mood and a normal healthy attitude.
- 5-HTP promotes the production of Serotonin, a hormone responsible for emotional well-being and regulation of carbohydrate and fat intake and digestion in the diet.
- Let 5-HTP 50 MG give you the power to take personal control over the state of your mental health.

SAM-E:

- SAM-e is beneficial for: supporting mood and a normal healthy attitude; developing vital biological compounds to include hormones, proteins, and neurotransmitters, and catalyzing their biochemical reactions; regulating the desire to eat and sleep to support emotional well-being; raising energy levels and enthusiasm for everyday activities, to include time spent with family, work, and hobbies; providing minor pain relief; supporting the production of cartilage and overall joint health.

Kava Kava Extract:

- Exposed to psychological stressors through everyday activities, Kava simply installs a sense of calm and well-being, assisting one throughout daily tasks.
- Kava's sedative properties: induce sleep, limiting insomnia; reduce appetite, limiting caloric intake and assisting dieting; minimize worry, allowing the mind to problem solve without distraction; relax muscles, relieving pain and inflammation resulting from overwork or an injury.

Ginkgo Biloba Extract:

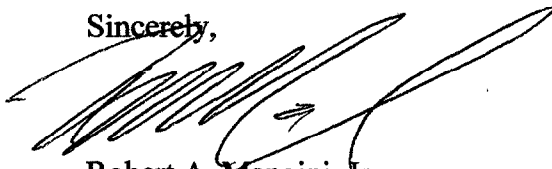
- It is a powerful antioxidant, defending against free radical damage to cellular systems, enriching vitality, and augmenting life expectancy.
- Ginkgo increases blood flow to the entire body, promoting alertness and strengthening cognitive awareness through oxygen circulation.
- Ginkgo Biloba is responsible for: balancing mood and acting as an up-lifter; reducing inflammation in the vascular system to smooth circulation; enhancing everyday brain functions including memory and reaction time; shielding environmental damage to the brain and central nervous system; protecting capillaries from becoming brittle, ceasing the development of spider veins and the deterioration of eye function; help maintain respiratory health.
- Ginkgo Biloba has shown to be helpful for those experiencing low energy levels, mental fatigue, and problems with concentration.
- Regular use of 1 capsule twice daily or as otherwise directed, Ginkgo Biloba Extract will repair insufficient circulation, energizing your brain, heart, and mind.

Circulatory Formula:

- Combining extracts of Ginkgo Biloba, Pine Bark, and Grape Seed, you have the necessary ingredients to: strengthen cell membranes and restructure blood vessel tone; increase flexibility in the capillaries of the brain and heart, smoothing blood flow; enhance circulation in the brain, sharpening short-term memory and other brain functions; develop thinner blood, assisting the cardiovascular and neurological systems; provide more potent free radical antioxidant activity than Vitamins C and E.
- Taking 1 capsule daily with meals, you challenge the aging process and enhance your life.

The undersigned certifies on behalf of PHN that the information contained in this notification is complete and accurate, and that PHN has substantiation that the foregoing statements are truthful and not misleading.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Mangini, Jr.', with a large, sweeping flourish extending from the end of the signature.

Robert A. Mangini, Jr.
President